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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,262	11/18/2005	Breda Mary Cullen	JJM0618USPCT	9333

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MORGAN, LEWIS & BOCKIUS LLP
1701 MARKET STREET
PHILADELPHIA, PA 19103-2921

EXAMINER	
KLINKEL, KORTNEY L	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,262	CULLEN ET AL.	
	Examiner	Art Unit	
	Kortney L. Klinkel	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-13 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/23/2009 has been entered. Claims 1, 3-13 and 19 are pending.

Withdrawn Claim Rejections

Claim Rejections - 35 USC § 112 1st Paragraph

The rejection of claims 1, 3-13 and 19 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of applicant's amendments to remove the new matter (i.e. the "consisting essentially of" language).

Claim Rejections - 35 USC § 103

The rejection of claims 1, 3, 4, and 19 under 35 U.S.C. 103(a) as being unpatentable over Watt et al. WO 98/00180 and in further view of Cullen et al. WO 00/33893 is withdrawn because upon closer examination, Cullen et al. teaches all the limitations of the claims. This fact is reflected in the below rejection. Therefore the teachings of Watt et al. were determined to be redundant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-7, 9, 12 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Guo et al. (US 7252837).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Guo teaches a wound dressing composition comprising an intimate mixture of a chitosan and an oxidized cellulose (see Example 4). More specifically, Example 4 discloses a patch comprising oxidized regenerated cellulose (ORC) and water soluble chitosan. The ORC is in the form of dispersed fibers (i.e. Surgicel Nu-Knit® fabric). Because the composition of Guo comprises all the requisite ingredients, it would necessarily be capable of carrying out the intended use for topical application, as

required by claim 4. The ORC and chitosan make up at least 50% by weight of the material on a dry weight basis, as per claims 6-7. As per instant claim 9, Example 4 states that the composition is a very flexible patch. Because no thickness is recited in claim 9, this patch can be considered a flexible film. With respect to claim 19, Guo teaches at col. 7, lines 54-63 that wound healing growth factors can be applied to the wound dressing as in the steps outlined in Example 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-13 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cullen et al. WO 00/33893.

Cullen teaches a sterile composition which can be used as a wound dressing (claim 19 and page 9, lines 6-10) comprising a polysaccharide selected from the group including oxidized celluloses and chitosans, and salts **and mixtures thereof** (claim 8). Page 5, final paragraph states that chitosans and cellulose derivatives are equally effective polysaccharides for use in wound dressing compositions. Cullen further teaches that oxidized regenerated cellulose (ORC) is especially preferred (page 6, lines 13-14, also claim 9). Examples 2-4 are directed to compositions comprising ORC and Example 5 shows an example comprising chitosan. More specifically Examples 2 and 4 are directed to a combination of ORC and collagen, whereas Example 5 contains a mixture of collagen and chitosan. The ORC of Example 2 is in the form of fibers. Furthermore, page 3, lines 27-28 state that it is preferable that the ORC is in the form of fibers, which reads on instant claim 3.

With respect to claim 4 which recites wherein said oxidized cellulose and chitosan are dispersed in a semi-solid or solid vehicle for topical application, Cullen teaches at page 8, lines 27-30 that the polysaccharide is preferably dispersed in a gel (i.e. semi-solid) or that the carrier is a solid matrix.

With respect to claims 6-7 which recite wherein the oxidized cellulose and chitosan together make up at least 25% or at least 50% by weight of the material on a dry weight basis, Cullen teaches in example 1 that the polysaccharide portion of the composition is at least 66% (the remainder of the weight 0-33% is made up of platelet derived growth factor). Furthermore, Cullen teaches a composition containing 80% by weight of ORC fibers (example 2).

With respect to claim 8 which requires that the composition further comprises from about 0.01 to about 5% by weight on a dry weight basis of one or more wound healing therapeutic substances, Cullen teaches from 0.1 to 10000 ppm (i.e. 0.00001 to 1%). This range overlaps with the claimed range.

Instant claim 13 recites wherein the wound dressing is sterile and packaged in a microorganism-impermeable container. Cullen teaches that preferably the sterile compositions are sterile packaged in a microorganism-impermeable container (page 9, 3rd paragraph).

Cullen does not specifically exemplify a composition comprising both oxidized cellulose and chitosan. However, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention to obtain a wound dressing composition comprising (i) chitosan and (ii) oxidized cellulose, more specifically ORC, because Cullen teaches a sterile composition which can be used as a wound dressing (claim 19) including a therapeutic peptide and a polysaccharide selected from the group consisting of oxidized celluloses, chitosans and salts **and mixtures thereof** (claims 1 and 8). Furthermore, ORC and chitosan are art recognized functional equivalents. "It is

prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven,* 626 F.2d 846, 850, 205 USPQ 1069, 1072. Accordingly, one of ordinary skill in the art would expect the combination of two art recognized materials useful in wound dressing compositions to yield a composition useful in wound dressings upon their combination.

Instant claim 9 states the wound dressing composition is a flexible film. In light of that addressed above and in addition to the fact that Cullen teaches a sterile composition in the form of a polymer film (claim 19), instant claim 9 is *prima facie* obvious over the teachings of the prior art due to the fact that a polymer film can be flexible. Due to the fact that the recited components of the claimed composition are substantially similar to those taught by Cullen in the prior art, there is a reasonable expectation that a film of the composition suggested by the prior art would also be flexible.

Instant claims 10 and 11 recite a range of oxidized cellulose to chitosan ratios respectively. Example 5 depicts a ratio of collagen to chitosan of 55/45. As addressed above, collagen, chitosan and ORC are art recognized functional equivlents, so it would be obvious to substitute collagen for ORC with a reasonable expectation for success. One would be motivated to do so since Cullen teaches that collagen and ORC are equally valid wound dressing materials. Further, it would have been in the capacity to one of ordinary skill in the art to mix the two polysaccharides in the stated ratios in

instant claims 10 and 11, based on the fact that both oxidized cellulose and chitosan have been shown to have the same function in this context. This is an optimization of ranges and as such is considered to be *prima facie* obvious when the general conditions of a claim, i.e. combining chitosan and oxidized cellulose for wound dressings, are disclosed in the prior art.

With respect to claim 19, Cullen teaches the steps of contacting a composition with a biological medium containing cell growth factors to bind the cell growth factors to the material and washing and drying the material having the cell growth factors bound thereto to form said active wound dressing material, see Procedure 1 beginning at page 20.

In conclusion, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention to obtain a wound dressing composition comprising (i) chitosan and (ii) oxidized cellulose, more specifically ORC because Cullen teaches a sterile composition which can be used as a wound dressing (claim 19) including a therapeutic peptide and a polysaccharide selected from the group consisting of oxidized celluloses, chitosans and salts and mixtures thereof (claims 1 and 8). Cullen demonstrates that not only does a composition consisting of oxidized cellulose function as a wound dressing, but also a composition consisting of chitosan. Cullen also states that mixtures of the two polysaccharides are suitable for use (claim 8). Thus, combining two things that are each respectively recognized as being suitable in the prior art for a given purpose, one would have a reasonable expectation of success upon their combination. Examiner acknowledges Applicants' data in Figures 1-2 and has

determined that this data is insufficient to overcome the instant rejection because the data contained in Figures 1-2 depict elastase and collagenase activity, respectively, versus time for a negative control (gauze), a positive control (collagen/ORC sponge) and instant claimed invention, ORC/chitosan and Applicants' claimed invention performs within error identical to the collagen/ORC sponge. This is what would be expected given the teachings of Cullen which unequivocally state that ORC, collagen and chitosan are equally effective wound composition materials. In the absence of evidence showing that collagen and not ORC is the active ingredient in the collagen/ORC sponge, Applicants' data further supports Examiner's arguments stated above. Namely that both oxidized cellulose and chitosan separately have been shown to be suitable for use in wound dressings, one of ordinary skill in the art would have a reasonable expectation of success upon their combination—as is shown in Applicants' Figures 1 and 2. In addition, Applicants' data in Figures 1-2 are not commensurate in scope with what is being claimed, because Applicants' data is limited to compositions comprising ORC/chitosan, whereas the majority of Applicants' claims do not require ORC.

Response to Arguments

Applicant's arguments filed 3/23/2009 with respect to the rejection of claims under Cullen et al. (WO 00/33893) have been fully considered, but are moot in light of the new grounds of rejection. However, the Examiner will address those arguments still relevant to the Cullen et al. reference.

Applicant argues that Cullen et al. does not teach, suggest or otherwise disclose a wound dressing composition comprising an intimate mixture of a chitosan and an

oxidized cellulose. This argument is not persuasive. Page 8, first paragraph states that the polysaccharide substrate, which from the teachings throughout the document, including claim 8 can be a mixture of chitosan and ORC, is intimately mixed with the peptide. Upon studying the examples in the Cullen reference, it is clear that an intimate mixture between the combination of polysaccharides is obtained. All ingredients are swollen and mixed together in an aqueous slurry. For example, the teachings of example 5 refer to the combination of collagen and chitosan as a complex. Please note that the methods utilized in Cullen et al. are identical to those of the instant specification, therefore an intimate mixture is necessarily obtained.

Applicant further argues that "it is a surprising and unexpected result of the present invention that such intimate mixing results in maximum chemical complexation between the amine groups of the chitosan and the carboxylate groups of the oxidized cellulose (page 5, lines 1-2)." This reaction, however, is by no means surprising or unexpected. It is well known that amines react with carboxylate groups to form amides. This reaction is thermodynamically very favorable, accordingly one would expect the simple combination of oxidized cellulose and chitosan in solution to chemically complex.

Applicant further argues that "it is a surprising and unexpected result that the intimate mixture of the present invention has an excellent ability to bind to growth factors - in particular, platelet derived growth factor (PDGF) (page 10, lines 10-15)." Again, this finding is neither surprising or unexpected based on the teachings of Cullen et al. Cullen et al. teaches that both ORC and chitosan bind PDGR, see examples 2 and 5 respectively. Furthermore, page 5, final paragraph teaches that cellulose

derivatives and chitosan are effective at stabilizing peptides against sterilization by ionizing radiation.

Applicant has provided no results to rebut the *prima facie* case of obviousness presented above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-7, and 9-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 7252837. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims are directed to a wound dressing comprising ORC and sodium carboxymethyl cellulose. The ratio of these two

ingredients ranges from about 1:99 to about 20:80 which overlaps with the ranges of instant claims 10-11. The ORC is in the form of fibers. The difference between the patented claims and the instant claims is that the patent utilizes sodium carboxymethyl cellulose rather than a chitosan as required by the instant claims. However, the final paragraph of column 4, continued onto column 5 teach that sodium carboxymethyl cellulose and chitosan and carboxymethyl chitosan are functional equivalents. This fact is further supported by the data presented in table 1 at columns 9-10. This table shows that ORC when mixed intimately with either sodium carboxymethyl cellulose or water soluble chitosan the same effect is observed (see Examples 4 and 5).

Claims 1, 3-5, 9, and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of copending Application No. 11/609964. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of application '964 comprise screen made of an intimate mixture of chitosan and ORC (i.e. a complex). The comprising language of the instant claims allows for the additional components recited in the claims of application '964.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 7-12 of

copending Application No. 10/579850. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of application '850 recite a wound dressing material comprising a polymeric substrate which is comprised of collagens, oxidized celluloses, chitosans, galactomannans, glycosaminoglycans and mixtures thereto (claim 2), or collagens, oxidized celluloses, chitosans and mixtures thereof (claim 3) or more specifically oxidized cellulose with a collagen, a chitosan or both a collagen and a chitosan (claim 11). Claim 12 of '850 recites wherein the wound dressing material according to claim 11 is sterile and packaged in a microorganism impermeable container. The claims of '850 specify the presence of a silver salt (i.e. a wound healing therapeutic substance). The claim scope of '850 is broader than the instant claims in the sense that a mixture of oxidized cellulose and chitosan is one of a handful of composition options. However, due to the limited number of possible combinations recited in the claims, it would have been obvious to have chosen the combination of oxidized cellulose and chitosan.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1, 3-13 and 19 are rejected. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611